

Virtual Mentor

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Medicine on TV

From the Editor

It Is Good Medicine	221
Audiey Kao, MD, PhD	

Case and Commentary

Is It Covered or Not? Health Plans and Experimental Procedures	224
Commentary by Kayhan Parsi, JD, PhD	

In the Literature

Clinical Use of Placebo	226
Keith Bauer, PhD, MSW	

AMA Code Says

Resuscitating Privacy in Emergency Settings	228
Audiey Kao, MD, PhD	

Art of Medicine

"Departed, Jan 11, 1983; At Peace, Dec 26, 1990"	231
Sara Taub, MA	

Personal Narrative

The Modern Plague	234
Robert Davidson, MD, MPH	
Through the Patient's Eyes: New Doctor	238
FR Burdett	
Through the Physician's Eyes: A First-Year Resident's Obstetrical Ethical Dilemma	240
Vickie Mello, DO	

Viewpoint

Do Not Resuscitate Orders: A Call for Reform	242
David E. Weissman, MD	
Use and Meaning of Medical Acronyms	247
Audiey Kao, MD, PhD	
Take One: the American Medical Association; Lights, Camera, Action	249
Kayhan Parsi, JD, PhD and Sara Taub, MA	
Protecting the Public: Profile of Dr. Frances Oldham Kelsey	252
Karen Geraghty	

Upcoming Issues of *Virtual Mentor*

August: Poets? Yes. Providers? No.
September: The Difficult Patient-Physician Relationship
October: Commemorating Virtual Mentor's First Two Years
November: Commemorating Virtual Mentor's First Two Years

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FROM THE EDITOR

It Is Good Medicine

Audiey Kao, MD, PhD

When we speak of good medicine, we typically mean the science of medicine and its clinical quality—is the doctor providing the most appropriate diagnosis and treatment for my illness? Over the past quarter century, advances in the medical sciences and subsequent improvements in the technical ability of physicians have resulted in our increasing ability to deliver good, science-based medicine. Undoubtedly, the day will come when the details of the Krebs cycle, information that almost all medical students have to learn, will be relevant to providing good medicine at the bedside.

Despite continuing scientific advances, the practice of good medicine requires more than applying the right science at the correct time for a specific ailment. Good medicine demands the practice of medicine as an art because there will always be the point at which our science simply cannot stop the inevitable, and, thus, compassion and comfort are all that physicians can provide to their patients in need. The challenge confronting the medical profession is how to educate physicians in not only the scientific but the artful practice of medicine.

In medical school, the art of medicine is taught in courses such as the doctor-patient relationship or professional ethics, and, compared to the course load in the sciences, the time and effort dedicated within the formal curriculum to the artful practice of medicine is limited and, some say, ineffectual. Factors in medical school that contribute to the challenges of teaching ethics and professionalism range from competing curriculum demands, inadequate support and training for teaching, student resistance to such courses, and the belief that no one can be trained to be compassionate by taking a course^{1, 2, 3, 4}. These same barriers are even more difficult to overcome during postgraduate training, where the educational environment of internship and residency oftentimes works against the further development and cultivation of the artful practice of medicine. These experiences in the undergraduate and graduate medical settings can lead to a "hardwiring" that makes professional attitudes and behavior among practicing physicians that much less modifiable.

Given the choppy landscape of ethics education and training, there is a growing realization and urgency among leaders in medicine that a more systematic approach must be developed for imparting ethics competencies and then evaluating whether individuals have obtained them^{5, 6, 7}. In short, it seems, paradoxically, that the art of

medicine must have a more scientific basis if it is to promote the practice of good medicine. Medical school faculty are increasingly more innovative as they refine ethics curricula, both formal and informal, to address the educational needs of students. The Accreditation Council for Graduate Medical Education has adopted core competencies that doctors-in-training in accredited residency program must demonstrate. Among these core competencies is the ability to provide ethical care, an accreditation requirement that should lead to structural reforms of the residency workplace that will foster the practice of compassionate care. Lastly, there appears to be a growing demand for ethics CME courses, and this trend will likely further accelerate as more states require these types of lifelong learning requirements for purposes of licensure.

A not-so-famous man once said, "If you can't measure it, it isn't important." In the case of good medicine, it is widely accepted that we need to measure how well physicians are providing clinical care so that we can continue to make improvements. I would argue that this logic applies not only to the science of medicine, but also in many important respects to the art of medicine—otherwise it simply becomes idealistic rhetoric. Today, given the tremendous challenges confronting medicine and the health care system, physicians are expected not only to be expert in the science of medicine, but to be proficient and competent in the art of medicine. Leaders in medicine must work together to develop innovative ways of imparting and evaluating the ethical skills and competencies of physicians. We hope that the Virtual Mentor has contributed to that endeavor for our readers, and we are working hard to develop more innovative means to promote and assess the ethics and professionalism of tomorrow's physicians. Stay tuned.

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CASE AND COMMENTARY

Is It Covered or Not? Health Plans and Experimental Procedures

Commentary by Kayhan Parsi, JD, PhD

Case

Dr. Burnett arrived at DeFrancis to examine Mrs. Raphael. He confirmed her blood Ms. Evans was diagnosed with stage II, node positive breast cancer. The primary tumor was 3 centimeters when diagnosed, and 14 of her 23 axillary lymph nodes were involved with the tumor. Ms. Evans underwent a lumpectomy, lymphadenectomy, and several months of standard-dose chemotherapy, all of which her health plan covered. Her physician, Dr. Bookman, discussed another possible follow-up treatment for her breast cancer. He believed that Ms. Evans' best chance for long-term survival required the administration of a procedure called high-dose chemotherapy/peripheral blood stem cell rescue (HDC/PBSCR). This is a three-step process. First, blood stem cells are harvested from the patient's circulating, or peripheral, blood and placed in temporary storage. Next, the patient undergoes a cycle of high dose chemotherapy in hopes of killing the cancer cells. After administration of the HDC, the stored blood stem cells, which also would have been attacked by the chemotherapy had they not been removed, are reinfused into the patient's bloodstream to relieve the toxic effects of the HDC.

Dr. Bookman requested that the health plan pre-approve payment of expenses for Ms. Evans' treatment. Part of the charge was for stem cell rescue procedure, but no CPT code existed for such a procedure. Moreover, the health plan determined that the HDC/PBSCR procedure was experimental and investigational in nature and should not be covered. This decision was made by a patient care committee composed of physicians employed by the health plan.

Questions for Discussion

1. Ms. Evans cannot afford the HDC/PBSCR treatment without reimbursement. Should Dr. Bookman use the code of a therapy that is listed on the CPT so that Ms. Evans can receive the therapy he thinks offers her the best chance of long-term survival?
2. Should physicians who are employed by the health plan serve on the patient care committee that makes reimbursement decisions?
3. "Mis-coding" for the procedure aside, does Dr. Bookman have any ethical or professional responsibility for attempting to help Ms. Evans receive payment for the HDC/PBSCR procedure that he believes will benefit her?

See AMA *Code of Medical Ethics* Opinion 8.13 regarding Managed care. *Code of Medical Ethics 1998-1999 Edition*. Chicago, IL: American Medical Association; 1998.

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The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental. The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.

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IN THE LITERATURE

Clinical Use of Placebo

Keith Bauer, PhD, MSW

Despite the dearth of evidence that placebos are clinically effective, they have been heralded throughout medicine's history as a means to relieve symptoms and contribute to the well-being of patients. Centuries of anecdotal evidence and a general belief in the efficacy of placebos as treatments were given "scientific" status in 1955 with Henry K. Beecher's research on placebos¹. However, Beecher's study and much of the subsequent research on placebo-controlled trials is limited by the fact that the primary comparison has been between the placebo and the trial therapy not between the placebo and no treatment at all. The problem with such a placebo-therapy design is that it cannot adequately distinguish a placebo effect from the natural fluctuations that often occur in the course of a patient's disease.

In "[Is the Placebo Powerless?](#) An Analysis of Clinical Trials Comparing Placebos with No Treatment," Asbjørn Hróbjatsson and Peter Gøtzsche circumvent the limitations of the placebo-therapy design by conducting a systematic review of 130 clinical trials in which approximately 7,500 patients with 40 different clinical conditions were randomly assigned to either placebo or no treatment and evaluated in terms of binary outcomes and continuous outcomes, objective and subjective. With the exception of some small subjective effects on the reduction of pain, the authors report that they found very little evidence of placebos having powerful clinical effects. They conclude that outside clinical trials, there is no justification for the use of placebos.

In a companion editorial to the Hróbjatsson and Gøtzsche article, John Baillor argues that their conclusion may be too broad and hasty². For one thing, some patients did report reductions in their experiences of pain with placebos. Second, there are both statistical and methodological doubts over the quality of some of the clinical trials included in Hróbjatsson and Gøtzsche's study. But Baillor mentions problems of his own concerning placebos—clinical and ethical problems. First, the use of placebos (versus no pill taking) could act as a regular reminder of a patient's illness. Rather than alleviating discomfort, placebos could increase patient discomfort. Second, placebos could mask symptoms and lead patients to not seek "real" treatments if they believe they are being treated. In both cases, the autonomy and well-being of patients could be undermined. Finally, placebos involve deception on the part of the physician that could deleteriously affect the physician-patient relationship.

Nevertheless Baillor leaves the door open for non-research placebo use. With the proviso that each and every clinical use of placebo demands justification, he concludes that their contribution to pain relief, particularly, "may merit their continued therapeutic use"².

Questions for Discussion

1. If we assume that placebos are sometimes clinically effective, can you think of circumstances in which (outside of clinical trials) their benefits for patients justify physician deception?
2. If so, on what grounds would you justify the deception?

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AMA CODE SAYS

Resuscitating Privacy in Emergency Settings

Audiey Kao, MD, PhD

Since the trend toward reality TV in medicine took off around 1997, 30 or more emergency departments have invited film crews in for "around-the-clock taping"¹. Many physicians and administrators at participating hospitals are pleased with the results. The reality shows, they say, counteract the glamorized portrayals in dramas such as *ER* that create unrealistic expectations for survival and recovery from trauma. Thus, they argue, the reality shows—*Trauma*, *Paramedics*, *Hopkins 24/7*, and the like—educate the public and demystify the emergency department encounter.

Not all physicians agree. Medical ethics rests on the bedrock understanding that those who are sick are vulnerable. This fundamental truth gives rise to the ethical and professional standards governing patient privacy and confidentiality as well as to a gravity of purpose and conduct that suffuses the clinical interaction.

Some physicians believe that making an entertainment of actual clinical encounters violates these ethical and professional standards. The presence of non-medical team members, they claim, invades patient privacy, exploits the sick and dying, and could compromise clinicians' ability to work most efficiently.

One physician who felt strongly about the exploitation of critically ill or injured—and therefore especially vulnerable—individuals was Dr. Martin Fujimura, whose one-man crusade helped spearhead a movement for change in AMA policy. A family practitioner in Dayton, Ohio, Dr. Fujimura began campaigning for change in the fall of 1999. He penned letters to the Ohio State Medical Association, published an article for *In Confidence* magazine², and wrote to the AMA Council on Ethical and Judicial Affairs (CEJA) requesting that the national organization of physicians develop a policy to curtail this practice of filming. "I am particularly saddened," his letter stated, "by what I perceive as the exploitation of patients who need our care and protection the most, i.e., the severely injured and the dying. How is it permissible to allow camera crews to film half-naked, dying patients (even teenagers and children) prior to obtaining consent?" he challenged.

In response to Dr. Fujimura's request, CEJA researched the topic and, in December 2000, solicited comments from the AMA's House of Delegates on the possible need for ethical guidelines governing patient filming. CEJA compiled the comments, drafted a recommendation, and presented it to the House of Delegates reference committee at the annual meeting in June 2001. The recommendation was approved,

adopted as AMA policy by the House, and will become part of the AMA *Code of Medical Ethics*.

In essence, the recent AMA policy on filming of patients in health care settings for the purpose of commercial broadcast states that doing so without consent is a violation of the patient's privacy³. Consent, says the policy, "is an ethical requirement for both initial filming and subsequent broadcast for public viewing." The report argues that, because filming cannot confer any therapeutic benefit to the patients, it is not worth the risk to patient privacy (and possibly well being) that it entails. Therefore, the policy states, "it is appropriate to limit filming to instances where the party being filmed can explicitly consent." Many trauma patients are unconscious or in distress too great to permit their giving informed consent. In such circumstances, the temptation is to allow the next of kin or other surrogate decision maker to provide consent. The report says this is not satisfactory. Consent by a surrogate health care decision maker is not an ethically appropriate substitute for consent by the patient because the role of such surrogates is to make decisions necessary for medical treatment or refusal of treatment. Consenting to or refusing to be filmed is not a medical treatment decision.

For most of the trauma and emergency room footage that has aired on television, patients' consent was received after the filming and before the broadcast. If patients did not consent, their portion of the film was not broadcast. But the filming itself had already violated their privacy. To understand why, it is necessary to distinguish between privacy and confidentiality. Patient privacy refers to the fact that patients are entitled to have only those individuals involved in their medical care examine them or observe their examination. AMA policy dictates that "physicians are ethically and legally required to protect the personal privacy and other legal rights of patients"⁴. Confidentiality, on the other hand, refers to what happens afterward to information shared in private with the physician. Patient records and conversations fall under this protection and give sanctity to the patient-physician relationship. Information that is shared with the physician should not be disclosed to others, according to AMA policy on confidentiality, without the patient's consent or unless the disclosure can be "ethically and legally justified by overriding social considerations"⁵. Examples of overriding social considerations include patient threats of harm to self or others from physical violence or communicable disease. Protection of privacy and confidentiality go hand-in-hand. If the patient-physician encounter is not private, confidentiality is far more difficult to secure.

Thus, unless a stationary camera is used or a health professional does the filming, the privacy of the clinical encounter is violated when filming takes place. Receiving consent for distributing the film after the fact avoids breaches of confidentiality but does nothing to undo the invasion of privacy. Breach of patient privacy is permissible only through expressed informed consent before filming.

It is important to recognize that, under the new AMA policy, patients who are conscious and able to give consent may be filmed. Even here, though, the report that

paved the way for the new policy warns that the time required for informing the patient fully about what the film crew may observe and record is time perhaps better spent on diagnosis and treatment.

As stewards of the AMA *Code of Medical Ethics*, the Council on Ethical and Judicial Affairs develops opinions on a variety of ethical and professional issues that confront physicians and recommends them to the House of Delegates each year for action. Any physician, any concerned individual, can bring a matter to the Council's attention. When Dr. Fujimura did so, CEJA transformed his interest in protecting emergency patients into an opinion of the Code, where it stands as a guide for physicians who strive to practice ethically.

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ART OF MEDICINE

"Departed, Jan 11, 1983; At Peace, Dec 26, 1990"

Sara Taub, MA

Nancy Cruzan died January 11, 1983, when she was but 25 years old. Unfortunately for her, for those who loved her, and indeed for all of us, she died at a time and in a place that does not recognize her death. Consequently, she has never been buried or cremated, but instead kept in a hospital bed for nearly seven years. High medical technology has sustained only the most rudimentary of her biological processes¹.

The inscription on Nancy Cruzan's gravestone (represented in the photograph above) and the message Professor Momeyer conveys in a viewpoint that ran less than a year before a lower court judge ruled Cruzan's feeding tube could be removed arrive at the same conclusion: Nancy Cruzan, the person, died seven years before her biological processes were allowed to cease and her body was let to expire. This young woman's life story was interrupted after she lost control of the vehicle she was driving on January 11, 1983. She was thrown 35 feet from the car into a barren field, where she landed face first and experienced approximately 15 minutes of anoxia. The paramedics who arrived at the scene of the accident were able to restore her heartbeat. Her cerebral cortex, the seat of awareness and thought, was irrevocably damaged—she would never regain higher brain function. Nancy, in her permanent vegetative state (PVS) could no longer experience anything of the world around her, except perhaps pain.

Determined to see their daughter at peace, her parents undertook a prolonged legal struggle that led all the way to the US Supreme Court. If they could obtain a court order to have her feeding tube removed, Nancy who was already "gone" could be put to rest. But they were confronted with the perspectives of others for whom life in any condition, sustained by whatever means, is of absolute value. To the latter, removal of the feeding tube would be morally wrong, as it would result in the patient's death. In addition, they argued, the action would open the door to killing people who no longer seemed of use to anyone².

By the time the Cruzan case reached the Missouri Supreme Court in 1988, that court had recognized a competent person's right to refuse treatment, as part of the doctrine of informed consent. For decisions to be made on behalf of an incompetent patient, however, the court required "clear and convincing" evidence that the patient would have wanted treatment terminated under such circumstances. The court decided to "err on the side of life," where what was at issue was not Nancy's "right to die," but the right of others to take her life. Judge Robertson's opinion read:

"Nancy is not dead, nor is she terminally ill. This is a case in which we are asked to allow the medical profession to make Nancy die by starvation and dehydration. The debate here is thus not between life and death. It is between quality of life and death"³.

In the majority opinion of the landmark 1990 case, the US Supreme Court broadened the ruling of the Missouri Supreme Court, though it still did not grant the Cruzans the victory they were after. The Court recognized a competent person's constitutionally protected right to refuse life-prolonging treatment (including hydration and nutrition). In the case of incompetent persons, a state could adopt a standard that required "clear and convincing" proof of a person's preferences⁴. At the request of the Cruzans' lawyer, the Missouri probate court reheard the case later in 1990, after new people stepped forward to provide evidence of Nancy's wishes. It ruled that there was sufficient evidence that Nancy would not want to be kept alive.

Beyond recognizing at the federal level that patients have the right to see their end-of-life care wishes honored, the Cruzan case, through the publicity it generated, brought the matter of PVS to public awareness. It asked people to give serious thought to what medical treatment, life support, and quality of life they would want should they become incapacitated. Further, it accelerated the development of concrete actions people could take to record their wishes and feelings:

- In 1991, as a result of the Cruzan decision, the federal government enacted the Patient Self-Determination Act that requires hospitals, nursing facilities, hospices, home health care programs, and health maintenance organizations to inform patients about their right to make forward-looking care and treatment decisions through the use of advance directives.
- Following the Cruzan case, states developed both medical proxy laws, whereby individuals could designate someone to make medical decisions for them if they become incapacitated, and living wills, legal statements of end-of-life care wishes

The legacy of the Cruzan case was to foster mechanisms to safeguard the interests of people who become incapacitated at the end of life. Others could avert the tragedy of the Cruzans—and free themselves of some of the fear around end-of-life. A recent article, however, points to the fact that few people take advantage of the options the case made available to them: only 10 percent have living wills to reflect their wishes around end-of-life care, should they become incapacitated⁵.

Still, Nancy Cruzan is responsible for a Supreme Court decision that helped to empower people—competent and incompetent—with choices at the end of life. "I think this is quite an accomplishment for a 25 year old kid," her father said, "and I'm damn proud of her."

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PERSONAL NARRATIVE

The Modern Plague

Robert Davidson, MD, MPH

Accurate statistics on the epidemic are hard to come by. The reporting system is getting better, but probably still under-reports. The United Nations Agency on AIDS [UNAIDS] provides the most comprehensive data. Their January 2001 data estimate a total prevalence of 25.3 million infected people living in sub-Saharan Africa, an estimate that represents 80 percent of all HIV+ persons in the world. The new case rate for 2000 was 3.8 million, down from 4 million new cases in 1999. In 8 countries in the region, at least 15 percent of the adult population is infected with the virus. Botswana, where the prevalence is estimated to be 35.8 percent of the adult population, has the worst statistics. The statistic that strikes me hardest is the estimate that 1/3 of all 15-year-olds in sub-Saharan Africa will die from complications of AIDS. The infection rate in teenage girls is 5 times higher than in teenage boys, although the boys begin to catch up during their 20s.

The economic impact is catastrophic. Sub-Saharan countries spend about 2-3 percent of their gross domestic product [GDP] on HIV / AIDS, in spite of the abysmal lack of treatment opportunities for most HIV+ Africans. The total spending on health in these countries averages only 3-5 percent of GDP. Dollars spent on HIV / AIDS tend to go for treatment in the later stages of the disease process. In Kenyatta Hospital in Nairobi, a large public hospital run by the government, 40 percent of all occupied beds are devoted to treatment of HIV / AIDS patients. In Burundi, that figure rises to 70 percent of the beds in the Prince Regent Hospital in Bujumbura. Since the disease strikes hardest during the working years, the loss of manpower extracts a heavy toll on the country's economy and productivity. UNAID estimates that in South Africa, as the disease progresses in the infected population, the total GDP will be reduced by 17 percent, which amounts to \$22 billion (US) wiped out of the economy annually.

The personal suffering is immeasurable. No one is unaffected by the impact of a family member, neighbor, or friend who has the disease or has died from it. The Peace Corps volunteers report a funeral a week—at least—in most villages, with the causes of death avoided in hushed tones. A walk through any African village on market day is a sobering experience. Emaciated women try to sell their wares while succumbing to the wasting process of AIDS. Men with oral thrush, thin arms, and probable dementia stand idly by. The elderly, who passed through their sexually promiscuous years before the epidemic, seem to take on a larger daily role. The specter of the children is the most horrific. Thin faces with no hope in their eyes

stare at life passing them by. The number of orphanages dedicated to abandoned children is growing. The traditional tribal family structure is overwhelmed and can no longer take in additional children from relatives who have died or are dying.

As I see it, there are 2 reasons that the epidemic has gotten so far in sub-Saharan Africa. One is the virulence and effect of the virus on the basic body defense system. The multitudes of infectious diseases that abound in Africa make immunocompromised persons easy targets. The more important factor, however, is the nature of transmission via sex. Many cultural beliefs and practices in Africa contribute to the easy transfer of the virus through sex. As I listen to rural men talking, I become aware of some of these beliefs. For example, many believe that if a man has sex with a virgin girl, he will be cured of the disease. Women are much more vulnerable in this culture. The process of improving their status and rights has only begun. Many men still believe, as did their fathers and grandfathers, that it is a man's right to have sex with whomever he wants. Women are often looked upon as property. The dowry or payment to the woman's family or tribe "buys" the woman for the man's family. If the man dies, a brother or other man of the husband's family can then claim the woman. Women have little capability to resist the sexual advances of the men of the community. Thus, the 5 times higher rate of HIV infection in teenage girls.

There Is Hope

In spite of the huge economic impact and human cost, there is hope. The human spirit is amazingly resilient. I recently attended a "conversion" party at a Nairobi orphanage. Children born to HIV+ mothers carry the mother's antibodies to HIV and therefore test positive, although they may not be infected with the virus. As they clear the maternal antibodies, they sero-convert to negative status, and the nurses and caregivers celebrate. There are some encouraging signs that inroads are being made on the disease. In Uganda, often referenced as a country on the right track, the estimated prevalence rate of HIV+ persons was down to 8 percent in 1999 from a peak of 14 percent in the early 1990s. Most African governments now acknowledge the AIDS epidemic and support or at least allow prevention programs. Billboards, TV commercials, and hastily drawn signs promoting use of safe sex practices abound. The strong oral tradition in Africa expresses itself in effective messages from traditional community theatre. Such theatres are increasing in number and influence.

There are things that can be done. In Uganda's success story, 2 two factors contribute to the reduction in new cases. The first and more important is the growing acceptance of condoms, now readily available in the most remote villages, and the continual message from media and oral tradition messengers re-enforcing their use. The second factor is the increasingly availability of low cost, community-based testing centers. The development of these centers was supported by international aid money. Its donors were smart enough to use community groups to develop and run the testing and counseling centers. The contrast between the lack of hope in villages in Kenya and the heartwarming support and optimism displayed in

the community testing centers in Uganda is impressive. I really do not think the epidemic will be stopped in Africa until an effective vaccine is found. In the interim, however, there is much that can be done.

Treatment Dilemmas

The HIV / AIDS epidemic presents several treatment dilemmas. A major controversy exists, for example, regarding the use of anti-retroviral drugs. They are readily available in Africa, but at a price far beyond most people's ability to pay. If the struggling government health systems tried to buy the drugs needed, even at so called "cost," it would literally bankrupt the system and probably the country. One can argue on the side of a moral imperative to treat, but the reality is quite different. A better use of money for medications would seem to be the relatively cheap antibiotics available to combat and help prevent the secondary infections. Readily available generic antibiotics would go a long way toward reducing 2 of the biggest killer infections: TB and pneumocystis carinii pneumonia (PCP). The retro-viral drugs could best be used in reducing HIV transmission from mother to infant through maternal treatment prior to birth. Pre-natal retro-viral treatment could reduce the infection rate in newborns by an estimated 50 percent.

Breast feeding by HIV+ mothers is another dilemma. It is known that breast milk carries the virus. The rate of untreated maternal-child transmission of the virus in Africa varies from 25-45 percent depending on the population. This is much higher than in industrialized countries where the untreated rate is estimated at 15-20 percent. US studies have shown that breast feeding by an HIV+ mother raises the risk that the child will be HIV+ by 14 percent. Two studies in Africa have shown that breast-feeding raises the rate of children who are positive to 50 percent. On the other hand, if the child does not breast feed, then he or she is exposed to the numerous bacteria and parasites in the usually untreated water supply. Several studies have shown as high as a tripling of the infant death rate in children who are not breastfed. The current WHO recommendation recognizes this dilemma and advises HIV mothers to breast feed their babies for 6 months and then wean them from breast milk. This seems like a reasonable compromise.

In no way do I mean to minimize the effects and suffering in the US from the HIV virus. However, the impact on daily life is of such a greater magnitude in Africa that it is incomprehensible without actually being in the center of it. To paraphrase Yoda of the Star Wars series, "There is a grave disturbance in the galaxy." We all must find some way to contribute to combating this modern plague.

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Virtual Mentor

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PERSONAL NARRATIVE

Through the Patient's Eyes: New Doctor

FR Burdett

New insurance. Another HMO—second in my first year of Medicare. I can't remember how many primary care physicians I've had since they started calling them that.

I arrive 20 minutes early for the first appointment with the new PCP, aware there is a woman waiting to thrust a clipboard and forms at me. Where do they find all of them—the forms and the women? I am still writing and making check marks 10 minutes after my appointment time. How many different ways are there to probe for employment, a working spouse—potential additional insurance coverage?

Age? Date of birth? Why both? She's already made copies of my driver's license and insurance card. Normal weight? 200. Weight gain/loss in past year? Plus 10 pounds. Height? At my best, I was 6 foot 3/4 inches; now I barely measure five eleven and a half. I hate to admit I'm not 6 foot anymore so I write "6'0." Maybe they won't catch it.

Married? Single? Widowed? Divorced? What's the difference between divorced and single? What is the need to know? Do single organs fail or function differently from divorced (or widowed or married) organs? Will it mean I'm strange if I say "single"? Or a failure if I check "divorced"? I feel single. I've been divorced twice, but I've been single three times—in all, a couple more years than I was married. I like feeling "single." I check that. The relationship of my emergency contact is "son" but I'm single. Does that matter anymore?

There are the standard questions about medications, allergies, illnesses, and surgeries. Here's one I haven't seen before: Sexually active? Not very. Sex of partners? Clearly they mean partner's sex. Wonder what the grace period is? I check "not sexually active"—reluctantly. It's not like I've given up hope. Sex of partners: "N/A."

Then the biggie. I like the way the Blood Bank asks it: Have you had sex with a male, or someone who's had sex with a male who has sex with other males, since 1976? (Something like that anyhow.) I'm always tempted to ask which month.

The rest aren't quite so invasive. Yes, I have noticed a loss of vision and hearing—seems like memory too. Yes, I have ringing in my ears, insomnia, and I snore. I also

have shortness of breath, pains in my calves—and other assorted pains they don't ask about. There are a lot of things I don't like to admit even to myself but I keep checking them off. I really thought I was pretty healthy when I came in. I remind myself I'm not sick; I'm just here for an initial visit, referrals to my dermatologist and ophthalmologist, a new thyroid prescription, and a flu shot.

The good news is I stopped smoking and drinking and I have a regular exercise program. They ask about my Living Will and Durable Power of Attorney for Healthcare. I've brought copies of those and my organ and whole body donation and Do-Not-Resuscitate Order. Now the wait.

Over an hour past the appointed time, I am weighed in—214.80 with clothes. They don't check my height; I get by with that. They lead to me an exam room where the doctor joins me shortly. From the table, I look down at the top of his head as he reviews the list I brought along of things I thought were pertinent; his remarks are limited almost entirely to "fines," "very goods," and "excellents." I scrutinize him more thoroughly than he scrutinizes me. He's very bald but his red facial hair is thick and dark. He must be young enough that he will still be around when I need him, but that doesn't seem important in this day of revolving doctors.

He doesn't take my blood pressure or listen to my heart. He doesn't examine me—or look at me closely. The snap of latex gloves is conspicuous by its absence. Even my prostate feels slighted. He hasn't touched me except to shake my hand. No eye contact either.

He doesn't look at the forms I filled out. What are they going to do with those? Was it only that woman who was curious? In less than 10 minutes I have the referrals and prescription and am headed to the lab for a thyroid check on my way out.

The phlebotomist tells me I made a good choice of doctors. Maybe. Maybe this is patient-directed medicine. Maybe I'll like him if I get to know him. Maybe I should have brought a form for him to fill out. The jury is still out. I mean how can I tell? Actually I chose him for the proximity of his zip code. And he did originate the referrals and give me the prescription I asked for. That's all I really needed today—that and the flu shot I forgot to ask about and he didn't mention either.

FR Burdett walks the seawall and writes in Galveston, an island off Texas, in the Gulf of Mexico. His PCP is located 30 miles inland.

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PERSONAL NARRATIVE

Through the Physician's Eyes: A First-Year Resident's Obstetrical Ethical Dilemma

Vickie Mello, DO

The expectations we give women about when they are "supposed" to deliver can have powerful effects on their mental health. Most women get very anxious when they go past their due dates. In fact, some women try to manipulate and pressure their physicians into inducing their labor. After all, they are tired of being pregnant.

I found myself in the middle of a particularly difficult plea-to-induce situation during my first year of OB/GYN residency. Should I empathize with my patient who has stuck it out the full 40 weeks and attempt to induce labor because she is "hurting every time the baby moves"? Or should I play by the rules, stick to my guns, and only induce labor for medical indications as put forth by the American Academy of Obstetrics and Gynecology? At heart, I am probably what you would call a naturalist. Let nature take its course as long as the baby seems to be doing well. The first ethical rule we learned in medical school was "do no harm," and the patient is at 40 weeks and 2 days gestation by our best calculations (a first trimester ultrasound). So, I reassured the patient that her non-stress test (NST) looked good, and there was no indication that anything was wrong.

A couple days later she called with left upper quadrant pain, mostly in her ribs. I reassured her that this was very normal and that she would be seen in the office in a couple of days. But again, she asked why she couldn't just be induced, "get it over with already." I asked myself, would it really do any harm to start a little Pitocin? She was already dilated to 2cm with a very "inducible" cervix. She was a "multi-p" who should have no problem.

In the back of my mind were the medico-legal issues that never seem to go away. If I induce labor and something goes wrong, any kind of bad outcome, how can I defend my decision to electively induce labor? On the flip side, suppose I refuse to induce labor after she has asked me at least twice? If there is a bad outcome, no matter if it could have been prevented or not, the patient will remember my insensitivity to her pleas. Would I regret not following her wishes? Then there are the cost issues. Will the insurance company pay for an elective induction just because the patient is tired of being pregnant? But which is more costly, repeated NSTs or a little Pitocin? I don't really have an answer.

There are 2 schools of thought among the obstetricians practicing in this institution. There are those who think, "Hey, I might as well induce her now instead of waiting and delivering her Saturday night while I'm trying to have dinner with my family. Besides, she's taken care to make all her prenatal appointments and she really is uncomfortable." Then there are the obstetricians who believe they must hold the line and keep order. "We cannot let the patients control how we practice medicine." This group believes that guidelines are there for a reason and the doctors must occasionally protect their patients from themselves. After all, what would the labor and delivery nurses think of them for inducing this lady just because she's tired of being pregnant? Would I join the group of doctors who get made fun of for listing "prevention of postdates" as an indication for inducing labor?

It was a hard spot to be in as a young doctor trying to do the right thing. Actually, when the patient called to complain about her ribs, it was Friday night. I reassured her and realized that I would again be on call the following Monday. I suggested she try and hang in there until then, but come in sooner if the pain got too bad. On Monday, she was still pregnant at 41 weeks gestation. She was scheduled for an NST and, when I went to talk to her, found that she had missed the appointment. So, unsure about what to do next, I spoke to the attending physician. To my own relief, not to mention the patient's, he said to bring her in for induction. She received IV Pitocin and we delivered her healthy baby about 5 hours later. Although everything worked out well for this 18-year-old woman delivering her third child, I was left with one conclusion: No 2 pregnant women are the same, and, depending on the situation, I might do something entirely different the next time.

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VIEWPOINT

Do Not Resuscitate Orders: A Call for Reform

David E. Weissman, MD

I recently conducted my monthly teaching session with the oncology ward team; I asked what it was they wanted to talk about within the broad realm of *palliative care*. The unanimous answer: "DNR orders." I asked why, knowing full well their answer. They said, "We know it's required under hospital policy to ask patients their preference about resuscitation, but these cancer patients . . . well . . . you know . . . they're dying . . . it doesn't make sense." Designed to ensure patient autonomy while at the same time identifying patients in whom resuscitation is not indicated, DNR orders have become an example of how a well-meaning application of modern medical ethics has led to untold patient/family suffering and, less appreciated but quite significant to the issue of improving end-of-life care, health professional distress.

The Problem with DNR Orders

Institutional DNR policies were developed prior to any sustained effort at health professional education concerning the communication skills necessary to implement such policies. This failure to provide appropriate education has in part been responsible for fueling the problem. Commonly heard phrases such as, "would you like us to do everything if your heart stops?" or "what would you like us to do if you stop breathing?" or "you don't want us to break your ribs, do you?" should be permanently banned from the health professional lexicon. Jim Tulskey, MD has done some of the most elegant research on DNR and advanced directive communication skills; his findings are not pretty^{1,2,3}. In one study of DNR orders, he found that in discussions between 31 medical residents and patients, only 4 physicians discussed the likelihood of survival and only 5 mentioned the risks of resuscitation².

Although increasing attention has focused on education, the question remains whether or not education itself, as an instrument of practice change, is the most appropriate avenue to improve the DNR problem⁴. What type of education is required in order to fix the DNR problem? A cursory review of the educational domains needed for mastery of the skill of DNR discussions in the setting of a terminal illness, includes demonstration of basic and advanced medical interviewing skills; demonstration of ability to give unwanted news and discuss treatment limitation; understanding prognostic factors for chronic diseases; understanding the risks, benefits, appropriate indications and contra-indications for the medical procedure of cardio-pulmonary resuscitation; and, finally and perhaps most importantly, the ability of the clinician to self-reflect on the personal meaning

of treatment limitation and the finality of caring for a dying patient. The reason for so many diverse educational domains is that *DNR discussions should always take place within a larger framework of an advanced care planning discussion, a discussion that includes disease prognosis and mutually agree-upon goals of care.* And yet, despite this daunting list of necessary skills, who is most likely to be entrusted, or rather, assigned, to discuss DNR orders in teaching hospitals?—the lowest person in the medical hierarchy—the intern, if not the junior or senior medical student. Why? Because, the discussion of DNR represents an unsolvable contradiction for the physician, resulting in a level of distress that makes avoidance of the task a desired goal. Senior physicians routinely pass the responsibility down the line to those who are least able to refuse. When is the last time you saw senior residents lining up for the chance to "go get the DNR order"?

No matter where I go and teach about end-of-life care, the same theme emerges—a sense among physicians and nurses of being forced by institutional policy, reinforced by the fear of medical malpractice, to discuss DNR issues in the face of imminent death from "natural causes." Forget for a moment that doctors often have poor communication skills and that they fail to appropriately contextualize DNR orders within the larger goals of care for the dying—it is the very nature of being forced to do something that *feels* wrong, that is such burden to the clinician. Why should we expect clinicians to feel good about caring for the dying when they feel pressured, by the real or perceived threat of malpractice or institutional sanctions, to offer a medical procedure they know is not only useless, but downright harmful? Should we continue efforts to teach communication skills around advanced care planning? Absolutely. But, I have now come to believe that the inherent tension of the current paradigm, whereby clinicians feel an obligation for mandatory DNR discussions in all patients, cannot be resolved solely by education. We must seek DNR policy reform that brings the reality of CPR as a medical intervention in line with the professional responsibility of caring for the dying.

Proposed Policy Reform

What would DNR policy reform look like? First and foremost it would acknowledge that physicians are not required to discuss the procedure of CPR, in all its gory details, in the setting of expected death. Writing a DNR order in this setting, without a complete discussion of the risks/benefits and purpose of CPR, is well within the capacity of an attending physician. Whether or not any discussion of CPR is needed in this setting is still considered highly contentious, although some hospitals have adopted so called "unilateral DNR orders," sometimes requiring two physicians to agree or an ethics committee consultation, or notification of the decision to the patient/surrogate and/or hospital administration^{4, 5, 6}. A middle ground approach is to talk to patients/surrogates about the goals of care and mention "breathing machines" or "life support" as a euphemism for CPR. Language that I often teach to resident physicians when discussing end-of-life goals and treatment options is: "I will provide you with maximal treatments for your pain or any other symptoms you may experience; I do not recommend the use of breathing machines or other artificial means to prolong your life." Note, this language

contains an explicit physician recommendation, and demonstrates appropriate professional leadership, rather than abrogating such leadership in favor of unrestrained patient autonomy (as in, "What would you like us to do if your heart stops?"). Whatever the exact phrasing used, I strongly support the notion that CPR does not have to be explicitly discussed when death is expected. Furthermore, I do not feel such a decision requires a mandatory ethics committee decision or notification of the patient/surrogate or hospital administration. Rather than external control to ensure that the order is appropriate, I favor a hospital policy that links recognition of impending death to an institutional commitment to end-of-life care—a formal family support/bereavement program that begins at the time death is anticipated and/or a mandatory visit by a palliative care nurse/team member to assess for adequacy of symptom control and discussion of care setting options.

But what about patient autonomy—doesn't this approach take an important decision away from the patient where it rightfully belongs? Tomlinson and Brody, discussing the authority of physicians to make decisions about futile treatments say, "physician authority over the use of futile treatment is the protection of patient autonomy . . . it is inherently misleading to offer a futile treatment, and so it is corrosive of autonomous choices to do so"⁷. But what about paternalism—won't this type of policy be dangerous by giving too much power to the clinician? Again, Tomlinson and Brody clearly articulate that the balance between patient autonomy and clinician paternalism is not "a zero-sum game: whenever the patient gains power, the physician loses it, and vice versa, but rather can be one of "shared power"⁷.

I could imagine a new DNR policy, added to an existing policy that discusses the important role of clinicians in setting the tone for routine advanced care planning, including DNR discussions, as something like this:

The attending physician may write a DNR order after a decision has been established between the physician and a decisional patient or surrogate that the goal of future medical care is to provide a level of care that does not interfere with the natural illness progression toward death. The application of this policy is appropriate in the following situations:

1. *When a life-prolonging medical treatment is withdrawn and the expected outcome is death (e.g. withdrawal of mechanical ventilation, or artificial hydration).*
2. *When patients exhibit signs and symptoms of the syndrome of "imminent death" (a.k.a. actively dying), in the setting of a terminal illness.*
3. *When patients with a chronic illness, or acute illness in the setting of a severe chronic illness, have declining functional ability so that death is expected within days-weeks.*

This type of policy would rightfully restore a measure of physician authority over a medical procedure and eliminate the paradox of offering a useless procedure in those situations where resuscitation and unrestrained patient autonomy have no role. However, this policy is by no means perfect. At issue is when and how it is decided that death will likely occur within days-weeks and whether or not physicians would abuse their responsibility by ignoring the central point of the policy—that a mutual decision to forgo life-prolonging medical treatment is

established as the goal of care, *prior to writing* the DNR order. Several options for dealing with this include establishment of a quality improvement system for DNR orders that would track usage and appropriateness, mandatory clinician education that includes demonstration of an end-of-life goal setting discussion (mandatory demonstration of the skill of actually performing CPR is already required, why not add the skill of discussing CPR!), and distribution of education material for patients/surrogates that explains the institutions' DNR policies.

I am eager to give such a policy a try as I see the current policy causing far more harm—patient/surrogate/staff conflicts, loss of professional authority over a medical decision, lack of attention to important end-of-life tasks, psychological harm to clinicians and families, patient indignity. There have been hundreds of thousands, if not millions of words written about DNR orders. I don't expect mine will be the last. I welcome your comments on both the need for DNR policy reform and suggestions for new policy initiatives. I would like to see palliative care practitioners take a leading role in working to define new DNR policies that better reflect the realities of care at the end of life.

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VIEWPOINT

Use and Meaning of Medical Acronyms

Audiey Kao, MD, PhD

- AMA stands for *anti-mitochondrial antibodies*. In addition, AMA stands for *against medical advice*, so the meaning of the acronym depends on the context of usage.
- CREST is an acronym that stands for *calcinosis, Reynaud's phenomenon, esophageal motility disorders, sclerodactyly, and telangiectasia*. CREST is often associated with other diseases such as primary biliary cirrhosis in which a circulating IgG AMA is detected in 90 percent of cases.
- TID is the Latin abbreviation for *ter in die* which means three times a day, and is used when prescribing medication. It is important to note that TID is not the same as every 8 hours, so physicians should be clear when writing prescriptions how frequently they intend their patients to take the prescribed drug.
- ICD-10 stands for *International Classification of Diseases 10th Revision*. ICD is the classification used to code and classify mortality data from death certificates compiled by the National Center for Health Statistics. It is designed to promote international comparability in the collection, processing, classification, and presentation of mortality statistics.
- CPT stands for [*Current Procedural Terminology*](#). Developed by the American Medical Association in 1966, CPT (based on a 5 digit numeric identifier) is a system for accurately coding medical, surgical, and diagnostic services, and is widely accepted as the nomenclature for the reporting of medical services under public and private health insurance programs. The current version of CPT contains nearly 8,000 codes and descriptors.
- ERCP stands for *endoscopic retrograde cholangiopancreatography*. The CPT 2001 code for diagnosing ERCP, with or without collection of specimen(s) by brushing or washing is 43260. If a gastroenterologist performs a biopsy then the code is 43261; if a sphincterotomy/papillotomy is performed, the code is 43262.
- SSSS stands for *staphylococcal scalded skin syndrome*. The acute phase begins with an erythematous rash originating periorbitally and periorally, that then extends to the trunk and limbs. Within hours or days, sloughing of the skin occurs which can be provoked by gentle stroking of the epidermis (Nikolsky's sign), even in areas that appear unaffected. Mortality usually from hypovolemia or sepsis is about 3 percent among children but can reach 50 percent among adults^{1, 2, 3}.

- SSS stands for *sick sinus syndrome*. SSS refers to a combination of symptoms (dizziness, confusion, fatigue, syncope, and congestive heart failure) caused by sinus node dysfunction and manifested by marked sinus bradycardia, sinoatrial block, or sinus arrest. This bradycardia is difficult to diagnosis because the symptoms are nonspecific and the ECG changes are frequently intermittent^{4, 5}.
- GOMER stands for *get out of my emergency room*, and is an acronym whose use should be abandoned.

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VIEWPOINT

Take One: the American Medical Association; Lights, Camera, Action

Kayhan Parsi, JD, PhD and Sara Taub, MA

A glance at your local television listings will quickly reveal that the interest in medical theme shows is not abating anytime soon¹. *ER*, the juggernaut of the 90s, is still watched by millions of people. Lately, as part of the "reality TV" trend, medical shows with a penchant for titillation have been filling the airwaves. These shows typically focus on individual physicians, nurses, and patients, with the hospitals playing a backdrop role. One show, *Hopkins 24/7*, gives the hospital itself a starring role. No television shows have featured the AMA in such a way. The inner workings of organized medicine certainly don't have the same appeal for the general public as the individual practice of medicine in the acute care setting, with its fast pace, heroic measures, and high stakes. Interestingly, however, the AMA has figured in the storylines of several recent programs, where it is offered as a symbol of organized medicine—either to emphasize notions of professionalism or, in a lighter vein, to poke fun at the power the institution of medicine has over our lives.

The AMA has never been a stranger to the media. Its journals' articles are frequently cited in the popular press. Policy decisions at its annual meetings are immediately disseminated by the major wire services. In addition, the AMA's achievements and setbacks are all thoroughly covered by the media. But lately the AMA's name has been popping up in some rather unlikely places: television sitcoms and dramas. Take, for instance, a recent episode of the highly popular *West Wing* in which one of the White House lawyers confronts the First Lady, Abigail Bartlet, who also happens to be a physician. Dr. Bartlet has surreptitiously written interferon prescriptions for her husband, the President, to help him conceal his MS diagnosis. The lawyer, played by Oliver Platt, states flatly that she violated Opinion 8.19 "Self treatment and treatment of immediate family members" of the AMA's *Code of Medical Ethics* by treating a family member. Further, she failed to maintain proper medical records—a violation of Code Opinion 7.05, "Retention of Medical Records" at which the lawyer only hints.

The AMA's code, in the lawyer's conversation with Dr. Bartlet, is invoked as an arbiter of proper physician conduct. Viewers familiar with the *Code* could glimpse its purple and gold cover in the presidential counsel's hand.

Sometimes, the AMA is invoked with an aura of deference. One of the tabloid television shows, *Extra*, recently devoted a segment to a rare disorder called

multiple chemical sensitivity (MCS). The segment focused on Cynthia Wilson, who offered testimony of her personal experience with MCS. The image then shifts from Ms. Wilson to the American Medical Association's official insignia. In the background a voice narrates: "Even the esteemed American Medical Association will not recognize this as a disease." The image of the association that this segment reflects is dual: on the one hand, its "esteemed AMA" suggests a prestigious body that sets the standard for what constitutes a disease (though in reality, the association does not play this role). On the other hand, it highlights the association's refusal to call MCS a disease, after the viewer has just heard how greatly the condition interferes with Ms. Wilson's physical and mental wellbeing. With little explanation given for the rationale behind the association's stance, the position seems uncaring towards the patient whose experience it does not validate.

A less serious invocation of the code comes in an episode of the *Simpsons* ("Pokey Mom" aired 1/17/01), where Homer creates the "miracle spine-o-cylinder," a device intended to help alleviate back pain (actually a trash can over which he shoves people backward). Chiropractor "goons" soon appear to rough up Homer ("stop chiropracting," they say)². In response, Homer reminds the goons that they are doing to him what the AMA did to them—trying to keep him out of the business and profession. "Think about the irony," Homer says repeatedly.

Another comic interpretation of the AMA occurred in an episode of the enormously popular sitcom *Seinfeld* ("The Package," aired 10/17/96). When Elaine, a *Seinfeld* regular, realizes her medical chart flags her as a difficult patient, she is determined to see this language eliminated, even if doing so requires her to steal the chart. Not long after a failed attempt at purloining the record, Elaine receives a phone call in the middle of the night. A cold, impersonal voice at the other end addresses her with a threatening tone: "We're with the American Medical Association, the AMA. Can you confirm the spelling of your last name?" Having obtained the desired information, her interlocutor rudely dismisses her questions before ordering her to hang up the phone to free the line so that he can make another call. Here, the AMA comes across as a policing agency that tracks down problem patients—either to deter them from "inappropriate" behavior or to reprimand them for it. The viewer is asked to believe, as the intrigue unfolds, that Elaine could very well be blacklisted by the AMA or penalized for her actions—when in fact it does not fall under the AMA's prerogative to do either to a patient. There is no question that *Seinfeld's* portrayal of the association is exaggerated, meant to evoke laughs from an extreme situation. Still, it's worth noting that the show plays on the idea of a patient-level enforcement role for the AMA.

These television shows use the AMA to tap into different ideas—perhaps even hostility—that viewers may have about the power medicine wields over our lives. In an effort to ridicule and, hence, make light of this power, the *Simpsons* and *Seinfeld* conjure exaggerated "big brother" images of enforcement as part of AMA activities. There is a sense that the shows' writers are playing off a staid, conservative image that often has characterized the association. The *West Wing* and

Extra direct the viewer's attention to a different AMA, one that is recognized for its standard setting and prestige. They invoke the association with very different intentions than the above mentioned comedies, as a model and standard for the profession of medicine. If there is one cohesive message in the diverse portrayals, it's that, whether someone wishes to mock or celebrate organized medicine, the AMA is the general public's emblem for it.

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VIEWPOINT

Protecting the Public: Profile of Dr. Frances Oldham Kelsey

Karen Geraghty

That Dr. Frances Oldham Kelsey saved countless lives and prevented numerous physical deformities of infants and children is a remarkable accomplishment in any career. More remarkable still is the fact that she accomplished this feat not through the discovery of a cure, the development of an innovative surgical procedure, or the invention of a life-saving device. Rather, it was Dr. Kelsey's professional behavior—her unwillingness to compromise the priorities of patient health and safety—that single-handedly averted an appalling tragedy nearly thrust upon an unsuspecting American public.

In September 1960, Dr. Kelsey was a newly appointed member of the Food and Drug Administration (FDA). Her very first assignment was to review the application for the drug Kevadon. Synthesized in 1954 and introduced to the market on October 1, 1957 in West Germany, the drug—known there by the name Thalidomide—was hailed as a wonder cure for insomnia. Non-addictive and non-toxic, Thalidomide induced sleep and was prescribed as a sedative that promised no side effects. As its popularity grew, it soon became the drug of choice prescribed to pregnant women combating symptoms associated with morning sickness. By 1960, Thalidomide was popularly prescribed throughout the world, including Europe and Canada.

The application by the Richardson-Merrell pharmaceutical company of Cincinnati to introduce Thalidomide under the brand name Kevadon to the US market reached the desk of Dr. Kelsey less than one month after her appointment to the FDA. Richardson-Merrell expected a routine approval for the drug. To Dr. Kelsey, the evaluation process for which she was responsible was anything but routine. Alarmed by the paucity of clinical evidence to support the drug's safety claims, she rejected the application with the request for more clinical evidence of its safety.

Of particular concern to Dr. Kelsey and her staff was one of the drug's major selling points: unlike barbiturates which induced sleep but also induced death if taken in large quantities, Thalidomide could be ingested in large quantities, seemingly without toxic side effects. However, Dr. Kelsey recalled a study she conducted on rabbits as a young post-doctoral pharmacologist at the University of Chicago in 1942. Part of a team that was seeking to create a synthetic cure for malaria, Dr. Kelsey had noted that, although adult rabbits metabolized quinine rapidly, pregnant rabbits were less able to metabolize the drug and embryonic rabbits had no ability

to metabolize the drug. Furthermore, Dr. Kelsey noted that the drug did indeed pass through the placental barrier between mother and developing fetus. Recalling those observations in reviewing the Thalidomide application, Dr. Kelsey was concerned that physiological changes such as pregnancy might change the absorption properties of Thalidomide, leading to harmful consequences.

Responding to Dr. Kelsey's requests for more clinical proof of the drug's safety, Richardson-Merrell submitted additional evidence, but she again rejected the application on the grounds that the reports were testimonial—not clinical—in nature.

As autumn closed in on the Christmas holiday season—the most lucrative time of the year for the sale of sedatives—the pharmaceutical company, frustrated by the repeated and, in their view, unnecessary delays, began to pressure Dr. Kelsey with visits and phone calls to her superiors. Despite the increasing pressure, Dr. Kelsey remained steadfast in her demand for thorough clinical studies demonstrating the drug's safety.

In December 1960, Dr. Kelsey read a letter published by the British Medical Journal that strengthened her skepticism regarding the safety claims of the drug. The letter was from a physician whose patients had taken Thalidomide over long periods of time and were now experiencing pain in their extremities. Concerned that this report was the first indication of toxicity effects, Dr. Kelsey continued to refuse to grant permission for marketing the drug in the US.

In the meantime, physicians throughout the world were beginning to report an unusual increase in births of severely deformed infants, particularly of infants born with the unusual condition of phocomelia. Although the first known casualty of Thalidomide—a child with severely deformed ears—was born on December 25, 1956 well before the mass marketing of the drug, the medical community was slow to recognize the link between Thalidomide and birth defects. It was not until November 1961 that a German pediatrician determined that 50 percent of mothers with deformed children had ingested Thalidomide in the first trimester of pregnancy. German health authorities pulled the drug from the market with other countries following its lead. By March 1962, faced with growing evidence against the use of Thalidomide, Richardson-Merrell Pharmaceutical company withdrew its application from the FDA in March 1962.

In the few years that the drug was on the world market, thousands of children were born with Thalidomide-related deformities. Many did not survive until their first birthday. Countless more miscarriages were traced to the use of Thalidomide. The damage in the United States, due to the work of Dr. Kelsey, was small by comparison, with 17 children documented to have Thalidomide-associated deformities. (During an investigational period, Richardson-Merrell had distributed more than 2.5 million Thalidomide tablets to more than 1,000 doctors who, in turn,

gave Thalidomide to nearly 20,000 patients, several hundred of whom were pregnant women.)

By refusing to compromise her exacting standards for patient safety, Dr. Frances Oldham Kelsey prevented what could have been a tragic outcome for thousands of children in the US. For her commitment to the professional ideal of patient health and safety, we are proud to name Dr. Frances Oldham Kelsey a role model in medicine.

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